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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,223	01/21/2000	Lori L. Carrigan	P04353US0	5582

27142 7590 10/20/2003

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 10/20/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/489,223

Applicant(s)

CARRIGAN, LORI L.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,12,20,21,25,33 and 41-58 is/are pending in the application.
- 4a) Of the above claim(s) 43-58 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4,20,33,41 and 42 is/are allowed.
- 6) ☒ Claim(s) 5-8,12,21 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 July 2003 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The rejections of claims 8, 11, 15, 19, 21, 24, 28, 32, 34, and 38-42 under 35 U.S.C. 112, 2nd paragraph, are withdrawn in light of the claim cancellations.
4. The rejection of claim 33 under 35 U.S.C. 112, 1st paragraph, is withdrawn in light of the insertion of the deposit information of inbred parents GE533340 and GE501400 into the specification.

Election/Restrictions

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- I. Claims 1-8, 12, 20, 21, 25, 33, 41, 42, drawn to hybrid maize seed designated 38A24; a maize plant or its parts produced from said seed; a tissue culture of regenerable cells of said plant; a maize plant regenerated from said tissue culture; said maize plant further comprising an introgressed cytoplasmic gene that confers male sterility; said hybrid maize plant wherein the genetic material contains one or more mutant genes or transgenes; a method of making hybrid maize plant 38A24 comprising crossing inbred maize plants GE533340 and GE501400; a method of producing a male sterile maize plant comprising transforming 38A24 with a transgene conferring male sterility, classified in class 800, subclass 320.1, for example.
- II. Claims 43-58, drawn to methods of making an F1 hybrid maize plant, comprising introgressing a mutant gene or transgene into at least one of two inbred maize plants, and then crossing the resultant plants to produce said F1 hybrid maize plant; a maize plant produced by said method, classified in class 800, subclass 260, for example.

Newly submitted claims 43-58, Group II, are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims are directed to methods that involve introgressing a gene into at least one of the parents of hybrid plant 38A24 and then crossing those plants, and the plant produced from that cross. The methods and products of Group I do not encompass introducing genes into the inbred parent

plants of 38A24. Further, the methods of Group II produce plants that are distinct from hybrid maize plant 38A24.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, Group I, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 43-58 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

6. Claims 8 and 21 are objected to under 37 CFR 1.75 (b) as being duplicate claims. Applicant is required to cancel one of the claims, or amend the claim(s).

Claim Rejections - 35 USC § 112

7. Claims 5-8, 12, 21, 25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5: the recitation "A tissue culture of regenerable cells or protoplasts of said cells" renders the claim indefinite. While protoplasts can be produced from cells, the cells themselves do not comprise protoplasts. It is suggested that the recitation, "or protoplasts of said

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cells be removed from the claim, and that a new claim be introduced directed to protoplasts produced from the tissue culture of claim 5.

In claim 6: the recitation, "or protoplasts of said cells having been isolated from a tissue" renders the claim indefinite. Tissues and cells of plants do not comprise protoplasts. It is suggested that the recitation, "or protoplasts of said cells" be deleted from the claim.

In claim 7: the recitation, "capable of expressing" in line 2 renders the claim indefinite. The recitation does not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed. It is suggested that the recitation be replaced with --having--.

In claims 8, 12, 21, 25: the claims are indefinite because they broaden the scope of the claim from which they depend. The plants of claims 2 and 20 do not encompass any introgressed genes. Claims 8, 12, 21, and 25 also do not present any methods steps indicating how the gene was introgressed into the plant of claim 2 or 20.

In claims 12 and 25: the recitation "mutant gene" in line 2 renders the claims indefinite. It is not clear if the mutant gene confers plant disease, insect, or herbicide resistance, or male sterility, to the plant.

8. Claims 8, 12, 21, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed June 30, 2003.

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Applicant traverses the rejection in the paper submitted July 23, 2003. Applicant's arguments have been fully considered but were not found persuasive.

The claims are broadly drawn towards a maize plant produced from hybrid maize seed designated 38A24, said plant further comprising an introgressed cytoplasmic gene the confers male sterility; or hybrid maize plant 38A24, or a maize plant having all the morphological and physiological characteristics of 38A24, further comprising any mutant gene or transgene introgressed therein, selected from the group consisting of plant disease resistance gene, insect resistance gene, herbicide resistance gene, and a male sterility gene.

The specification indicates that backcrossing is used to transfer specific desirable traits into an inbred line (paragraph bridging pages 3-4). The specification also indicates that pedigree breeding involves inbred lines (page 5).

However, the specification does not describe any 38A24 plants wherein one or more genes have been introgressed into the plant. The discussion of backcrossing and pedigree breeding in the specification is limited application to inbreds, which are then crossed to produce a new hybrid. The specification does not describe introgressing one or more genes directly into any hybrid plant.

Further, the specification does not describe any mutant genes of plant disease resistance genes, insect resistance genes, herbicide resistance genes, and male sterility genes. The specification also does not describe the function of any such mutant genes, as the nature of the mutated plant disease resistance genes, insect resistance genes, herbicide resistance genes, and male sterility genes are not described. The claims encompass all such mutant genes, including those that have yet to be isolated. Genes that have yet to be isolated cannot be described.

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Applicant argues that backcrossing has been known since the 1920's, and is the method preferred by breeders to introduce transgenes into already developed material. Applicants cite Poehlman et al. for indicating that backcross derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene added through the backcross. Applicants also refer to Wych, for discussing how male sterility is routinely backcrossed into an inbred line and how this is used to produce a sterile/fertile blend of an F1 hybrid (response, paragraph bridging pages 8-9). However, the claims indicate that the gene is introgressed into the hybrid, not into one of its inbred parents. Applicant also refers to another reference, Openshaw et al., and indicates that it was submitted with the reply (response, paragraph bridging pages 8-9). However, no such reference was submitted.

9. Claims 12 and 25 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards hybrid maize plant 38A24, or a maize plant having all the morphological and physiological characteristics of 38A24, further comprising any mutant gene or transgene introgressed therein, selected from the group consisting of plant disease resistance gene, insect resistance gene, herbicide resistance gene, and a male sterility gene.

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The specification does not describe any mutant gene of any plant disease resistance gene, insect resistance gene, herbicide resistance gene, or male sterility gene. There is no mention in the specification of any such mutant genes. This is a *NEW MATTER* rejection.

10. Claims 8, 12, 21, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards a maize plant produced from hybrid maize seed designated 38A24, said plant further comprising an introgressed cytoplasmic gene the confers male sterility; or hybrid maize plant 38A24, or a maize plant having all the morphological and physiological characteristics of 38A24, further comprising any mutant gene or transgene introgressed therein, selected from the group consisting of plant disease resistance gene, insect resistance gene, herbicide resistance gene, and a male sterility gene.

The specification indicates that backcrossing to transfer specific desirable traits into an inbred line (paragraph bridging pages 3-4). The specification also indicates that pedigree breeding involves inbred lines (page 5).

However, 38A24 is a hybrid plant. The specification does not teach how a gene can be introgressed into any hybrid plant. As crossing two different inbred corn plants produces 38A24, it is not clear how crossing 38A24 with another plant, and then using 38A24 as a recurrent parent can produce the claimed plants. Examples of introgressing a gene or trait into a hybrid plant are lacking in the relevant prior art. In the absence of further guidance, undue experimentation

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would be required by one skilled in the art to introgress one or more genes into hybrid maize plant 38A24. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

Further, the specification does not teach any mutant genes of any plant disease resistance gene, insect resistance gene, herbicide resistance gene, and male sterility gene. The function of such mutated genes are also not taught. It then is not clear how one skilled in the art is to use the claimed plants comprising introgressed mutant plant disease resistance genes, insect resistance genes, herbicide resistance genes, and male sterility genes. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

11. Claims 1-4, 20, 33, 41, and 42 are allowed. Claims 5-8, 12, 21, and 25 are rejected.

Claims 43-58 are withdrawn from consideration.


Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this

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application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

October 15, 2003

A handwritten signature in black ink, appearing to read 'Ashwin D. Mehta'.

Ashwin D. Mehta, Ph.D.
Primary Examiner
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